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UNCLAS SECTION 01 OF 02 BUCHAREST 000337

STATE FOR EUR/CE ASCHEIBE
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SENSITIVE
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SUBJECT: ROMANIA: REGULATIONS CHOKE PHARMA COMPANIES

REF: A) BUCHAREST 315; B) 08 BUCHAREST 607 AND PREVIOUS

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¶1. (SBU) Summary: American and other foreign pharmaceutical companies are upset that the Ministry of Health (MOH) has recently passed several ordinances which, taken together, severely impact their ability to operate profitably in Romania. With its "universal" healthcare system, the Government of Romania (GOR) has significant pricing power in the pharmaceutical market, which the MOH has consciously decided to use to force down costs. In order to sell medicines in Romania, pharmaceutical firms must certify to the Government that they are charging the "minimum European price," i.e., the lowest average price available in a basket composed of several EU countries, using a methodology and foreign currency exchange rate unilaterally determined by the MOH. Recently adopted rules also institute a price freeze for all drugs, including the drugs currently priced below the minimum European level. A separate, poorly conceived ordinance establishes a circular pricing methodology which interrelates generic and name brand prices in such a way that any price greater than zero theoretically violates the ordinance. Pharmaceutical firms are concerned that the ordinances in question were passed with no advance, and little subsequent, consultation with industry. The MOH appears secure in the knowledge that no one company can afford to exit the growing and highly competitive Romanian market, and is therefore willing to wring out cost savings by targeting the deepest pockets around-- multinational pharmaceutical firms.

¶2. (U) Post reported in ref A on proposed reforms to the Romanian health care sector. This cable, together with ref A, updates post's prior series of reports (ref B) on this sector. End Summary.

¶3. (SBU) In a letter sent to Health Minister Ion Bazac on March 17, 2009, the Association of Drug Manufacturers and Importers (ARPIM) asked for further bilateral discussions on three issues: 1) a clear methodology for updating the exchange rate; 2) the elimination of the "circular references" (see paragraph 5) between generic and name-brand medications; and 3) a calendar for raising the prices of pharmaceuticals that are currently sold below the minimum EU price level. MOH has not accepted any of these proposals to date. To illustrate the egregiousness of the problem on just the last point, one American company had agreed on a humanitarian basis to temporarily sell an anti-HIV drug at a loss in Romania. However, the MOH freeze on price increases has meant that the company now has to choose between selling indefinitely at a loss or withdrawing the product entirely-- a tough call when the medication is the only thing keeping some Romanian HIV-positive patients from developing full-blown AIDS.

¶4. (SBU) The fixed exchange rate for imported drugs established by the MOH has disproportionately affected American manufacturers whose

costs are denominated mostly in U.S. dollars. On February 1, the MOH determined that the official exchange rate forecast in the Government's 2009 budget of 4.00 RON/euro would be used to calculate the "minimum European price" for pharmaceuticals for the entire year. (The Government's budget forecast has since been revised to 4.3 RON/euro, but the Ministry's number has not been adjusted.) While this represents an improvement from the 3.63 RON/euro rate previously in effect, the RON was trading at 4.31 RON/euro when the rate was fixed and has remained above the reference rate since then. Major American firms with cost structures largely in dollars, such as Merck Sharpe and Dohme (MSD), operate at a competitive disadvantage to their European rivals (who are also suffering, but less severely), as they are forced to convert prices to RON at an arbitrarily fixed RON-euro exchange rate and then repatriate any profits at a floating RON-dollar rate. In essence, the weak RON has allowed the MOH to tack on an extra discount to the "minimum European price," wiping out already-slim profit margins.

¶5. (SBU) Pharmaceutical companies maintain that the combination of a disadvantageous exchange rate and "minimum European price" will cause the damage to their business to ricochet through other EU markets. As many of Romania's neighbors peg drug prices to a basket of prices in other countries (using Romania as a reference), Romania's artificially low price forces prices lower in other EU markets. Furthermore, the fixed exchange rate creates a potential arbitrage opportunity for distributors to purchase pharmaceutical products in Romania and export them at a profit to other EU countries. The lack of intra-European border controls makes the extent of the latter problem hard to track, but isolated instances have been uncovered.

¶6. (SBU) MOH's new rules applying to generic pricing are even more objectionable on commercial grounds. The MOH requires that brand

name medications be sold at no more than a 35 percent mark-up over generic competitors, while generic drugs are required by law to be sold at no more than 65 percent of the price of a brand name drug. The net effect of this "circular reference" pricing policy is that the only price at which both criteria can mathematically be met is zero. Any other price puts companies in violation of one of the ordinances, as it is impossible for a product to be no more than 35 percent more expensive than a competitor, when the competitor is required to charge no more than 65 percent of the name brand. Despite repeated interventions on the part of companies, this requirement has remained in place and the Ministry has shown no inclination to adjust the rules or further clarify how these ordinances are to be implemented.

¶7. (SBU) Comment: Post is coordinating with other foreign missions on this issue, and there is a general agreement on the need to address at least the generic pricing question on a high-level basis. In this instance, the American firms seem the worst off overall and they have been the most active in pushing the European firms to act in concert with them. The one point of consensus, however, is that the Ministry has neglected to consult with stakeholders in advance and is enforcing rules which are harmful and discriminatory toward all pharmaceutical importing companies. This lack of consultation underlines the importance of post's continued engagement on the issue. From both a commercial and policy standpoint the harm being done to American pharmaceutical companies in Romania is significant. Furthermore, the crack-down on medication is short sighted in a country which experiences high rates of chronic illness. If the MOH's actions force firms to exit from or reduce their exposure to the Romanian market, it is ultimately the patients who will bear the brunt of having access to lifesaving medications curtailed. End Comment.

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